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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,322	10/31/2001	James R. Komorowski	AMBIINC.008A	3387

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EXAMINER
PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
1654	7

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/001,322	Komorowski et al.
Examiner	**Art Unit**
Patricia Patten	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Jan 28, 2003* .

2a) [X] This action is **FINAL.** 2b) [ ] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-9* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *1-9* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [ ] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) [ ] Interview Summary (PTO-413) Paper No(s). _____
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

DETAILED ACTION

Claims 1-9 remain pending in the Application. An examination of the pending claims follows.

Claim Rejections - 35 USC § 102

Claims 1-2 and 7-8 remain rejected under 35 U.S.C. 102(e) as being anticipated by Carthron (US 6,277,842).

Applicants' arguments were fully considered, but not found persuasive.

Applicants' principal argument resides in the contention that because the claims state 'consisting essentially of' a chromium complex and alpha-lipoic acid, and because Carthron (US 6,277,842) ('842) disclosed additional constituents in the composition; i.e., chromium, coenzyme Q10 and niacin for example, Carthron does not anticipate the Instant claims.

Applicants point out that L-carnitine and pyruvate found in '842 both aid in loss of body fat and decreasing appetite respectively (p.3). Applicants debate that the

additional components disclosed by Carthron 'substantially influence the pharmacological effect of the composition' (p.3-Arguments). However, as indicated in the MPEP, and reiterated by Applicants, 'consisting essentially of' limits the scope of a claim by excluding additional materials or steps that ***materially affect the basic and novel characteristics of the invention***. Here, it is noted that the Invention, the claimed invention, is drawn to a composition ***with no stated intended use for the composition***. Even if the claimed Invention specifically recited an intended use such as 'for treating diabetes', would the additional ingredients actually effect the basic and novel characteristics of the invention?

Additionally, although claim 1 states 'consisting essentially of', it is clear from claims 8 and 9 that the chelating agent such as nicotinic acid is important to the composition. Thus, Applicants' arguments with regard to 'consisting essentially of' are further confusing in this regard. Applicant is stating that the additional ingredients found in Carthron would negatively impact the Instantly claimed invention, and yet the claims themselves evidence the fact that nicotinic acid plays a positive role in the functionality of the composition. Thus is another reason that the term 'consisting essentially of' is not understood in the claims as Instantly drafted.

It is deemed that the additional ingredients found in Carthron *would not effect* the basic and novel characteristics of the Invention. Absent sufficient evidence to the contrary, it is deemed that the alpha-lipoic acid as well as the chromium complex in the

composition would act *in-vivo* to increase glucose uptake while being unaffected by the additional constituents. Additionally, constituents which decrease appetite and loss of body fat would actually aid in the treatment of diabetes; i.e., a reduction in food would necessarily lead to decreased glucose levels, and obesity tends to aggravate diabetes. Thus, the incorporation of ingredients such as L-carnitine and pyruvate would actually contribute to the efficacious treatment of diabetes.

"If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) MPEP § 2163. It is deemed that Applicant has not submitted sufficient evidence to clearly establish that the additional constituents found in '842 would actually effect the basic and novel characteristics of the Invention, and therefore, the claims remain rejected over '842.

Claim Rejections - 35 USC § 103

Claims 1-4 and 6-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Carthron (US 6,277,842) for the reasons set forth in the previous Office Action.

Claims 1-9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Carthron (US 6,277,842) in view of de la Harpe et al. (US 5,980,905).

With regard to claims 1-4 and 6-9 as being unpatentable over Carthron, the motivation was clearly established in the previous office action. Claims 6 and 9 are drawn to an enteric coating of the composition. Carthron taught the use of coated tablets to delay disintegration in the gastrointestinal tract. The ordinary artisan would have had a reasonable expectation that an enteric coating would have been a suitable coating to delay disintegration in the gastrointestinal tract. The patent to Carthron specifically taught the incorporation of nicotinic acid which is a chelating agent, and specifically suggested the inclusion of carriers.

Applicants' arguments were considered, but not found convincing.

With regard to claims rejected over Carthron in view of de la Harpe et al., Applicants argue that the Examiner has not provided ample motivation to combine the references of Carthron and de la Harpe et al., and contends that there is 'absolutely no teaching or indication in either reference to remove the at least seven other possible

bioactive components from a pharmaceutical composition to combine a chromium complex, alpha-lipoic acid, and a cyclooxygenase inhibitor, acid, mucolytic, or salicin containing herb and arrive at the composition of the present invention" (p.4-Arguments). Again, as indicated *supra*, it is the opinion of the Examiner that Applicants have not provided substantial evidence which would clearly indicate that the additional components in Carthron would actually effect the basic and novel characteristics of the Invention. Further, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). (p.5-Arguments). In the Instant case, as clearly indicated in the previous Office Action, motivation of the combination of the references was made solely with regard to

the suggestions within the references, as well as common knowledge known by the ordinary artisan and not from knowledge gained in the Instant specification.

It is noted that the de la Harpe et al. was cited to support the coating of the composition on a microbead. It is deemed that because the patent of '842 envisioned various means of administration which were within the boundaries of the Invention, that the incorporation of microbeads in the composition of '842 would have been well within the purview of the ordinary artisan. It is further noted that the inclusion of a microbead, as a carrier would not have changed the basic and novel characteristics of the claimed Invention, seeing as the carrier is an inert vehicle for pharmaceutical delivery.

Claims may be allowable if amended to read 'consisting of' rather than 'consisting essentially of'. The inclusion of 'consisting of' would necessarily limit the claims to only containing the recited ingredients, and would overcome the '842 reference.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda

Brumback is on 703-306-3220 The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon P. Weber, Ph.D.
Primary Examiner